



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPPT-2016-0737; FRL- 9945-01-OCSP]**

### **Trichloroethylene (TCE); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and seeking public comment on a draft revision to the risk determination for the trichloroethylene (TCE) risk evaluation issued under TSCA. The draft revision to the TCE risk determination reflects the announced policy changes to ensure the public is protected from unreasonable risks from chemicals in a way that is supported by science and the law. In this draft revision to the risk determination EPA finds that TCE, as a whole chemical substance, presents an unreasonable risk of injury to health when evaluated under its conditions of use. In addition, this revised risk determination does not reflect an assumption that all workers always appropriately wear personal protective equipment (PPE). EPA understands that there could be occupational safety protections in place at workplace locations; however, not assuming use of PPE reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, or their employers are out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health." This revision, when final, would supersede the condition of use-specific no unreasonable risk determinations in the November 2020 TCE risk evaluation (and withdraw the associated order) and would make a revised determination of unreasonable risk for TCE as a whole chemical substance.

**DATES:** Comments must be received on or before **[INSERT DATE 30 DAYS AFTER**

**PUBLICATION IN THE *Federal Register*].**

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-EPA-HQ-OPPT-2016-0737, through the *Federal eRulemaking Portal* at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* Katelan McNamara, Office of Pollution Prevention and Toxics (7404M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-4361; email address: [McNamara.Katelan@EPA.gov](mailto:McNamara.Katelan@EPA.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, use, disposal, and/or the assessment of risks involving chemical substances and mixtures. You may be potentially affected by this action if you manufacture (defined under TSCA to include import), process (including recycling), distribute in commerce, use or dispose of TCE, including TCE in products. Since other entities may also be interested in this draft revision to the risk determination, EPA has not attempted to describe all the specific entities that may be affected by this action.

*B. What is EPA's authority for taking this action?*

TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation (PESS) identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C. 2605(b)(4)(A). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that provide instruction on chemical substances that must undergo evaluation, the minimum components of a TSCA risk evaluation, and the timelines for public comment and completion of the risk evaluation. TSCA also requires that EPA operate in a manner that is consistent with the best available science, make decisions based on the weight of the scientific evidence, and consider reasonably available information. 15 U.S.C. 2625(h), (i), and (k).

The statute identifies the minimum components for all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation to be conducted, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C. 2605(b)(4)(D). The statute further provides that each risk evaluation must also: (1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on relevant potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified hazards and exposures. 15 U.S.C. 2605(b)(4)(F)(i) through (ii) and (iv) through (v). Each risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii).

EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Pursuant to such authority, EPA is reconsidering the risk determinations in the November 2020 TCE Risk Evaluation.

*C. What action is EPA taking?*

EPA is announcing the availability of and seeking public comment on a draft revision to the risk determination for the risk evaluation for TCE under TSCA, which was initially published in November 2020 (Ref. 1). EPA is specifically seeking public comment on the draft revision to the risk determination for the risk evaluation where the agency intends to determine that TCE, as a whole chemical, presents an unreasonable risk of injury to health when evaluated under its conditions of use. The Agency's risk determination for TCE is better characterized as a whole chemical risk determination rather than condition-of-use-specific risk determinations. Accordingly, EPA would revise and replace section 5 of the risk evaluation for TCE where the findings of unreasonable risk to health were previously made for the individual conditions of use evaluated. EPA would also withdraw the order issued previously for 2 conditions of use previously determined not to present unreasonable risk.

This revision would be consistent with EPA's plans to revise specific aspects of the first ten TSCA chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. Under the draft revision, the same 52 conditions of use would continue to drive the unreasonable risk determination for TCE. Removing the assumptions that workers always and appropriately wear PPE (see Unit II.C.) when making the whole chemical risk determination for TCE would not alter the conditions of use that drive the unreasonable risk determination for TCE, though additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures would also drive the unreasonable risk in many of those conditions of use (where previously those conditions of use

were identified as presenting unreasonable risk for chronic non-cancer effects and cancer). Overall, 52 conditions of use out of 54 EPA evaluated would drive the TCE whole chemical unreasonable risk determination due to risks identified for human health. The full list of the conditions of use evaluated for the TCE TSCA risk evaluation is in Tables 4-59 and 4-60 of the risk evaluation (Ref. 2).

*D. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

## **II. Background**

*A. Why is EPA re-issuing the risk determination for the TCE risk evaluation conducted under TSCA?*

In 2016, as directed by TSCA section 6(b)(2)(A), EPA chose the first ten chemical substances to undergo risk evaluations under the amended TSCA. These chemical substances are asbestos, 1-bromopropane, carbon tetrachloride, C.I. Pigment Violet (PV 29), cyclic aliphatic bromide cluster (HBCD), 1,4-dioxane, methylene chloride, n-methylpyrrolidone (NMP), perchloroethylene (PCE), and trichloroethylene (TCE).

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for TCE in November 2020. The risk evaluations included

individual unreasonable risk determinations for each condition of use evaluated. EPA issued determinations that particular conditions of use did not present an unreasonable risk by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 (Ref. 3) and other Administration priorities (Refs. 4, 5, and 6), EPA reviewed the risk evaluations for the first ten chemical substances, including TCE, to ensure that they meet the requirements of TSCA, including conducting decision making in a manner that is consistent with the best available science.

As a result of this review, EPA announced plans to revise specific aspects of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby help ensure the protection of human health and the environment (Ref. 7). To that end, EPA is reconsidering two key aspects of the risk determinations for TCE published in November 2020. First, following a review of specific aspects of the November 2020 TCE risk evaluation, EPA proposes that making an unreasonable risk determination for TCE as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation, is the most appropriate approach to TCE under the statute and implementing regulations. Second, EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6, even though some facilities might be using PPE as one means to reduce workers exposures; rather, the use of PPE would be considered during risk management as appropriate.

Separately, EPA is conducting a screening approach to assess potential risks from the air and water pathways for several of the first 10 chemicals, including this chemical. For TCE the exposure pathways that were or could be regulated under another EPA administered statute were excluded from the final risk evaluation (see section 1.4.2 of the November 2020 TCE risk evaluation). This resulted in the ambient air and ambient water pathways for TCE not being assessed. The goal of the recently-developed screening approach is to remedy this exclusion and

to identify if there are risks that were unaccounted for in the TCE risk evaluation. While this analysis is underway, EPA is not incorporating the screening-level approach into this draft revised unreasonable risk determination. If the results suggest there is additional risk, EPA will determine if the risk management approaches being contemplated for TCE will protect against these risks or if the risk evaluation will need to be formally supplemented or revised.

This action pertains only to the risk determination for TCE. While EPA intends to consider and may take additional similar actions on other of the first ten chemicals, EPA is taking a chemical-specific approach to reviewing the risk evaluations and is incorporating new policy direction in a surgical manner, while being mindful of the Congressional direction on the need to complete risk evaluations and move toward any associated risk management activities in accordance with statutory deadlines.

*B. What is a whole chemical view of the unreasonable risk determination for the TCE risk evaluation?*

TSCA section 6 repeatedly refers to determining whether a chemical *substance* presents unreasonable risk under its conditions of use. Stakeholders have disagreed over whether a chemical substance should receive: A single determination that is comprehensive for the chemical substance after considering the conditions of use, referred to as a whole-chemical determination; or multiple determinations, each of which is specific to a condition of use, referred to as condition-of-use-specific determinations.

The proposed risk evaluation procedural rule was premised on the whole chemical approach to making an unreasonable risk determination (Ref. 8). In that proposed rule, EPA acknowledged a lack of specificity in statutory text that might lead to different views about whether the statute compelled EPA's risk evaluations to address all conditions of use of a chemical substance or whether EPA had discretion to evaluate some subset of conditions of use (i.e., to scope out some manufacturing, processing, distribution in commerce, use, or disposal activities), but also stated that "EPA believes the word 'the' (in TSCA section 6(b)(4)(A)) is best

interpreted as calling for evaluation that considers all conditions of use.” (Ref. 8).

The proposed rule, however, was unambiguous on the point that an unreasonable risk determination would be for the chemical substance as a whole, even if based on a subset of uses. (See Ref. 8 at pgs. 7565-66: “TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether ‘a chemical substance’ presents an unreasonable risk of injury to health or the environment ‘under the conditions of use.’ The evaluation is on the chemical substance—not individual conditions of use—and it must be based on ‘the conditions of use.’ In this context, EPA believes the word ‘the’ is best interpreted as calling for evaluation that considers all conditions of use.”). In the proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (Ref. 8 at pg. 7480).

The final risk evaluation procedural rule stated (82 FR 33726, July 20, 2017) (FRL-9964–38) (Ref. 9): “As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.” (See also 40 CFR 702.47). For the unreasonable risk determinations in the first ten risk evaluations, EPA applied this provision by making individual risk determinations for each condition of use evaluated in each risk evaluation (i.e., the condition-of-use-specific approach to risk determinations). That approach was based on one particular passage in the preamble to the final risk evaluation procedural rule, which stated that EPA will make individual risk determinations for all conditions of use identified in the scope. (Ref. 9 at pg. 33744).

In contrast to this portion of the preamble of the final risk evaluation procedural rule, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. In the key regulatory provision excerpted earlier



from 40 CFR 702.47, the text explains that, “[a]s part of the risk evaluation, EPA will determine whether *the chemical substance* presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents” (Ref. 9, emphasis added). Other language reiterates this perspective. For example, 40 CFR 702.31(a) states that the purpose of the rule is to establish the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B). Likewise, there are recurring references to whether the chemical substance presents an unreasonable risk in 40 CFR 702.41(a). See, for example, 40 CFR 702.41(a)(6), which explains that the extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk. Notwithstanding the one preambular statement about condition-of-use-specific risk determinations, the preamble to the final rule also contains support for a risk determination on the chemical substance as a whole. In discussing the identification of the conditions of use of a chemical substance, the preamble notes that this task inevitably involves the exercise of discretion on EPA’s part, and “as EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance—not just individual uses or activities—presents an unreasonable risk.” (Ref. 8 at pg. 33729).

Therefore, notwithstanding EPA’s choice to issue condition-of-use-specific risk determinations to date, EPA interprets its risk evaluation regulation to also allow the Agency to issue whole-chemical risk determinations. Either approach is permissible under the regulation. A panel of the Ninth Circuit Court of Appeals also recognized the ambiguity of the regulation on this point. *Safer Chemicals v. EPA*, 943 F.3d 397, 413 (9th Cir. 2019) (holding a challenge about “use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in

the manner Petitioners fear”).

EPA plans to consider the appropriate approach for each chemical substance risk evaluation on a case-by-case basis, taking into account considerations relevant to the specific chemical substance in light of the Agency's obligations under TSCA. The Agency expects that this case-by-case approach will provide greater flexibility in the Agency’s ability to evaluate and manage unreasonable risk from individual chemical substances. EPA believes this is a reasonable approach under TSCA and the Agency’s implementing regulations.

With regard to the specific circumstances of TCE, as further explained in this notice, EPA proposes that a whole chemical approach is appropriate for TCE in order to protect health and the environment. The whole chemical approach is appropriate for TCE because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle—from manufacturing (including import), processing, commercial and industrial use, consumer use, and disposal) for health of workers, occupational non-users, consumers, and bystanders associated with TCE exposures. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation, a substantial amount of the conditions of use drive the unreasonable risk; therefore, it is appropriate for the Agency to make a determination for TCE that the whole chemical presents an unreasonable risk.

As explained later in this document, the revisions to the unreasonable risk determination (section 5 of the risk evaluation) would be based on the existing risk characterization section of the risk evaluation (section 4 of the risk evaluation) and would not involve additional technical or scientific analysis. The discussion of the issues presented in this **Federal Register** notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior TCE risk evaluation and the response to comments document (Ref. 10). With respect to the TCE risk evaluation, EPA intends to change the risk determination to a whole chemical approach without considering the use of PPE and does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk

evaluation in the risk characterization section of the risk evaluation. EPA views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence per TSCA sections 26(h) and (i).

EPA is announcing the availability of and seeking public comment on the draft superseding unreasonable risk determination for TCE, including a description of the risks driving the unreasonable risk determination under the conditions of use for the chemical substance as a whole. For purposes of TSCA section 6(i), EPA is making a draft risk determination on TCE as a whole chemical. Under the proposed revised approach, the “whole chemical” risk determination for TCE would supersede the no unreasonable risk determinations for TCE that were premised on a condition-of-use-specific approach to determining unreasonable risk. When finalized, EPA’s revised unreasonable risk determination would also contain an order withdrawing the TSCA section 6(i)(1) order in section 5.4.1 of the November 2020 TCE risk evaluation.

*C. What revision does EPA propose about the use of PPE for the TCE risk evaluation?*

In the risk evaluations for the first ten chemical substances, as part of the unreasonable risk determination, EPA assumed for several conditions of use that all workers were provided and always used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA considered reasonably available information such as public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., Occupational Safety and Health Administration (OSHA) requirements for protection of workers).

For the November 2020 TCE risk evaluation, EPA assumed that workers used PPE for 21 occupational conditions of use. However, in the November 2020 TCE risk evaluation, EPA determined that there is unreasonable risk to workers for all these COUs even with this assumed PPE use.

EPA is revising the assumption for TCE that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. When characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. This approach of not assuming PPE use by workers considers the risk to potentially exposed or susceptible subpopulations (workers and occupational non-users) who may not be covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place.

In addition, EPA believes it is appropriate to evaluate the levels of risk present in scenarios considering applicable OSHA requirements (e.g., chemical-specific permissible exposure limits (PELs) and/or chemical-specific PELs with additional substance-specific standards) as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. Consistent with this approach, the November 2020 TCE risk evaluation characterized risk to workers both with and without the use of PPE. By characterizing risks using scenarios that reflect different levels of mitigation, EPA risk evaluations can help inform potential risk management actions by providing information that could be used during risk management to tailor risk mitigation appropriately to address any unreasonable risk identified, or to ensure that applicable OSHA requirements or industry or sector best practices that address the unreasonable risk are required for all potentially exposed or susceptible subpopulations (including self-employed individuals and public sector workers who are not covered by an

OSHA State Plan).

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, however, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practices related to PPE use is consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA proposes to make a determination of unreasonable risk for TCE from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because many of OSHA's chemical-specific permissible exposure limits largely adopted in the 1970's are described by OSHA as being "outdated and inadequate for ensuring protection of worker health" (Ref. 11), or because EPA finds unreasonable risk for purposes of TSCA notwithstanding OSHA requirements.

In accordance with this approach, EPA is proposing the draft revision to the TCE risk determination without relying on assumptions regarding the occupational use of PPE in making the unreasonable risk determination under TSCA section 6; rather, information on the use of PPE as a means of mitigating risk (including information received from industry respondents about occupational safety practices in use) would be considered during the risk management phase as

appropriate. This would represent a change from the approach taken in the 2020 risk evaluation for TCE and EPA invites comments on this draft change to the TCE risk determination. As a general matter, when undertaking risk management actions, EPA intends to strive for consistency with applicable OSHA requirements and industry best practices, including appropriate application of the hierarchy of controls, when those measures would address an identified unreasonable risk, including unreasonable risk to potentially exposed or susceptible subpopulations. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum applicability of TSCA while avoiding the imposition of duplicative requirements. Informed by the mitigation scenarios and information gathered during the risk evaluation and risk management process, the Agency might propose rules that require risk management practices that may be already common practice in many or most facilities. Adopting clear, comprehensive regulatory standards will foster compliance across all facilities (ensuring a level playing field) and assure protections for all affected workers, especially in cases where current OSHA standards may not apply or be sufficient to address the unreasonable risk.

Removing the assumption that all workers always and appropriately wear PPE in making the whole chemical risk determination for TCE would not result in additional conditions of use to the original 52 conditions of use that drive the unreasonable risk, though EPA would identify additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures as driving the unreasonable risk within many of those conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects and cancer due to assumed use of PPE). The draft revision to the risk determination would clarify that EPA does not rely on the assumed use of PPE when making the risk determination for the whole substance. EPA is requesting comment on this potential change.

#### *D. What is TCE?*

TCE is a colorless liquid with a pleasant, sweet odor resembling that of chloroform. It is

considered a volatile organic compound and has a wide range of uses in consumer and commercial products and in industry. An estimated 84% of TCE's annual production volume is used as an intermediate in the manufacture of the hydrofluorocarbon, HFC-134a, an alternative to the refrigerant chlorofluorocarbon, CFC-12. Another 15% of TCE production volume is used as a degreasing solvent, leaving approximately 2% for other uses. The total aggregate production volume decreased from 220.5 to 171.9 million pounds between 2012 and 2015.

*E. What conclusions did EPA reach about the risks of TCE in the 2020 TSCA risk evaluation and what conclusions is EPA proposing to reach based on the whole chemical approach and not assuming the use of PPE?*

In the 2020 risk evaluation, EPA determined that TCE presents an unreasonable risk to health under the following conditions of use:

- Manufacturing: domestic manufacture;
- Manufacturing: import;
- Processing: processing as a reactant/intermediate;
- Processing: incorporation into a formulation, mixture or reaction product;
- Processing: incorporation into articles;
- Processing: repackaging;
- Processing: recycling;
- Industrial and commercial use as a solvent for open-top batch vapor degreasing;
- Industrial and commercial use as a solvent for closed-loop batch vapor degreasing;
- Industrial and commercial use as a solvent for in-line conveyORIZED vapor degreasing;
- Industrial and commercial use as a solvent for in-line web cleaner vapor degreasing;
- Industrial and commercial use as a solvent for cold cleaning;
- Industrial and commercial use as a solvent for aerosol spray degreaser/cleaner and mold release;
- Industrial and commercial use as a lubricant and grease in tap and die fluid;

- Industrial and commercial use as a lubricant and grease in penetrating lubricant;
- Industrial and commercial use as an adhesive and sealant in solvent-based adhesives and sealants; tire repair cement/sealer; mirror edge sealant;
- Industrial and commercial use as a functional fluid in heat exchange fluid;
- Industrial and commercial use in paints and coatings as a diluent in solvent-based paints and coatings;
- Industrial and commercial use in cleaning and furniture care products in carpet cleaner and wipe cleaning;
- Industrial and commercial use in laundry and dishwashing products in spot remover;
- Industrial and commercial use in arts, crafts, and hobby materials in fixatives and finishing spray coatings;
- Industrial and commercial use in corrosion inhibitors and anti-scaling agents;
- Industrial and commercial use in processing aids in process solvent used in battery manufacture; process solvent used in polymer fabric spinning, fluoroelastomer manufacture and Alcantara manufacture; extraction solvent used in caprolactam manufacture; precipitant used in beta-cyclodextrin manufacture;
- Industrial and commercial use as ink, toner and colorant products in toner aid;
- Industrial and commercial use in automotive care products in brake parts cleaner;
- Industrial and commercial use in apparel and footwear care products in shoe polish;
- Industrial and commercial use in hoof polish; gun scrubber; pepper spray; other miscellaneous industrial and commercial uses;
- Consumer use as a solvent in brake and parts cleaner;
- Consumer use as a solvent in aerosol electronic degreaser/cleaner;
- Consumer use as a solvent in liquid electronic degreaser/cleaner;
- Consumer use as a solvent in aerosol spray degreaser/cleaner;
- Consumer use as a solvent in liquid degreaser/cleaner;



- Consumer use as a solvent in aerosol gun scrubber;
- Consumer use as a solvent in liquid gun scrubber;
- Consumer use as a solvent in mold release;
- Consumer use as a solvent in aerosol tire cleaner;
- Consumer use as a solvent in liquid tire cleaner;
- Consumer use as a lubricant and grease in tap and die fluid;
- Consumer use as a lubricant and grease in penetrating lubricant;
- Consumer use as an adhesive and sealant in solvent-based adhesives and sealants;
- Consumer use as an adhesive and sealant in mirror edge sealant;
- Consumer use as an adhesive and sealant in tire repair cement/sealer;
- Consumer use as a cleaning and furniture care product in carpet cleaner;
- Consumer use as a cleaning and furniture care product in aerosol spot remover;
- Consumer use as a cleaning and furniture care product in liquid spot remover;
- Consumer use in arts, crafts, and hobby materials in fixative and finishing spray

coatings;

- Consumer use in apparel and footwear products in shoe polish;
- Consumer use in fabric spray;
- Consumer use in film cleaner;
- Consumer use in hoof polish;
- Consumer use in toner aid; and
- Disposal.

Under the proposed whole chemical approach to the TCE risk determination, the unreasonable risk from TCE would continue to be driven by risk from those same conditions of use. In addition, by removing the assumption of PPE use in making the whole chemical risk determination for TCE, there are no additional conditions of use that would drive the draft unreasonable risk determination. The same 52 COUs out of the 54 EPA evaluated would

continue to drive EPA's unreasonable risk determination, though additional risks for acute non-cancer and cancer effects from inhalation and dermal exposures would drive the unreasonable risk within many of those conditions of use (where previously those conditions of use were identified as presenting unreasonable risk only for chronic non-cancer effects and cancer due to assumed use of PPE). Overall, 52 conditions of use out of the 54 EPA evaluated would drive the TCE whole chemical unreasonable risk determination.

### **III. Revision of the November 2020 Risk Evaluation**

#### *A. Why is EPA proposing to revise the risk determination for the TCE risk evaluation?*

EPA is proposing to revise the risk determination for the TCE risk evaluation pursuant to TSCA section 6(b) and consistent with Executive Order 13990, ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 3, 4, and 6). EPA is revising specific aspects of the first ten TSCA existing chemical risk evaluations in order to ensure that the risk evaluations better align with TSCA's objective of protecting health and the environment. For the TCE risk evaluation, this includes the draft revision: 1) making the risk determination in this instance based on the whole chemical substance instead of by individual conditions of use, and 2) emphasizing that EPA does not rely on the assumed use of PPE when making the risk determination.

#### *B. What are the draft revisions?*

EPA is releasing a draft revision of the risk determination for the TCE risk evaluation pursuant to TSCA section 6(b). Under the revised determination, EPA preliminarily concludes that TCE, as evaluated in the risk evaluation as a whole, presents an unreasonable risk of injury to health under its conditions of use. This revision would replace the previous unreasonable risk determinations made for TCE by individual conditions of use, supersede the determinations (and withdraw the associated order) of no unreasonable risk for the conditions of use identified in the TSCA section 6(i)(1) no unreasonable risk order, and clarify the lack of reliance on assumed use of PPE as part of the risk determination.

These draft revisions do not alter any of the underlying technical or scientific information that informs the risk characterization, and as such the hazard, exposure, and risk characterization sections are not changed except to the extent that statements about PPE assumptions in sections 2.3.1.2.5 (Dermal Exposure Modeling) and section 4.2.2 (Risk Estimation for Occupational Exposures), Table 4-9 (Inhalation Exposure Data Summary and PPE Use Determination), of the TCE risk evaluation would be superseded. The discussion of the issues in this notice and in the accompanying draft revision to the risk determination would supersede any conflicting statements in the prior executive summary and sections 2.3.1.2.5 and 4.2.2 from the TCE risk evaluation and the response to comments document (Refs. 2 and 10). Additional policy changes to other chemical risk evaluations, including any consideration of potentially exposed or susceptible subpopulations and/or inclusion of additional exposure pathways, are not necessarily reflected in these draft revisions to the risk determination.

*C. Will the draft revised risk determination be peer reviewed?*

The risk determination (section 5 in the November 2020 risk evaluation) was not part of the scope of the peer reviews of the TCE risk evaluation by the Science Advisory Committee on Chemicals (SACC). Thus, consistent with that approach, EPA does not intend to conduct peer review of the draft revised unreasonable risk determination for the TCE risk evaluation because no technical or scientific changes will be made to the hazard or exposure assessments or the risk characterization.

*D. What are the next steps for finalizing revisions to the risk determination?*

EPA will review and consider public comment received on the draft revised risk determination for the TCE risk evaluation and, after considering those public comments, issue the revised final TCE risk determination. If finalized as drafted, EPA would also issue a new order to withdraw the TSCA section 6(i)(1) no unreasonable risk order issued in Section 5.4.1 of the 2020 TCE risk evaluation. This final revised risk determination would supersede the November 2020 risk determinations of no unreasonable risk. Consistent with the statutory

requirements of TSCA section 6(a), the Agency would then propose risk management actions to address the unreasonable risk determined in the TCE risk evaluation.

#### **IV. References**

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER**

#### **INFORMATION CONTACT.**

1. EPA Draft Revised Unreasonable Risk Determination for TCE, Section 5, July 2022.
2. EPA Risk Evaluation for Trichloroethylene. EPA Document #740-R-18-008. November 2020. [https://www.epa.gov/sites/default/files/2020-11/documents/1.\\_risk\\_evaluation\\_for\\_trichloroethylene\\_tce\\_casrn\\_79-01-6.pdf](https://www.epa.gov/sites/default/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf).
3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register*. 86 FR 7037, January 25, 2021.
4. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register*. 86 FR 7009, January 25, 2021.
5. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register*. 86 FR 7619, February 1, 2021.
6. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register*. 86 FR 8845, February 10, 2021.
7. EPA Press Release. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. June 2021. <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.

8. EPA. Proposed Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register*. 82 FR 7562, January 19, 2017 (FRL-9957-75).

9. EPA. Final Rule; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act. *Federal Register*. 82 FR 33726, July 20, 2017 (FRL-9964-38).

10. EPA. Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE). November 2020. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0500-0114>.

11. Occupational Safety and Health Administration. Permissible Exposure Limits – Annotated Tables. Accessed June 13, 2022. <https://www.osha.gov/annotated-pels>.

**Authority:** 15 U.S.C. 2601 *et seq.*

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